



## IMRICOR ANNOUNCES FINANCIAL RESULTS FOR FY2023

### HIGHLIGHTS:

- Imricor capital equipment installed and patient recruitment underway at Johns Hopkins Hospital in Baltimore, USA for the VISABL-AFL clinical trial to support FDA approval. The US market is the largest by volume, and with quadruple the reimbursement rate of some European countries, presents a significant atrial flutter revenue opportunity for Imricor.
- GE HealthCare (GE) and Imricor signed a Master Services Agreement, wherein GE is paying Imricor to adapt Imricor products to work with GE HealthCare MRI systems. Completion of this work, combined with Imricor's existing relationships with Siemens and Philips, will make Imricor's products compatible with the vast majority of MRI scanners in target markets.
- Completed development work of NorthStar 3D mapping system, a vital piece of infrastructure to provide physicians with a consistent user experience across MRI platforms and to further enhance the value MRI guidance brings to the field.
- Formally established a collaborative partnership with Adis through the execution of a Joint Development Agreement, focused on seamlessly integrating state-of-the-art Artificial Intelligence (AI) modules developed by Adis into Imricor's advanced NorthStar 3D mapping system.
- Major milestones achieved in clinical trial programs:
  - VISABL-VT Trial: approved in Germany and the Netherlands, with local Ethics approval at one site, trial expected to commence in Q2 2024
  - VISABL-AFL Trial: received approval from US FDA to commence the study
  - Subsequent to this, Johns Hopkins Hospital IRB approved VISABL-AFL, with recruitment underway
- Expanded market presence in the Middle East:
  - Distribution agreement signed in Qatar with East Agency WWL (East Agency).
  - Distribution agreement signed in Kingdom of Saudi Arabia with Al Faisaliah Medical Systems (FMS)
  - Medical Device Marketing Authorization attained from the Saudi Food & Drug Authority
- Letter of Intent received from Pioneer Capital Fund to invest US\$8 million in Imricor in exchange for equity at a target price of US\$0.60 (A\$0.95) per share
- Multiple funding initiatives executed, providing Imricor runway to commence two global pivotal trials, as well as invest in growing its global hospital footprint
- Significant site activation activities:
  - Clinical Hospital Dubrava in Croatia placed an order for Imricor capital equipment, and installation is complete. Procedures to commence upon an MRI software license update from Siemens in Q2 2024
  - University Hospital Lausanne (CHUV) placed an order for Imricor capital equipment, scheduled to be installed in Q2 2024 in their brand new iCMR lab. The site will be a Centre of Excellence site, and will begin procedures as a VISABL-AFL clinical trial site
- An investor webinar will be held at 9.00am AEDT on Tuesday 5<sup>th</sup> March 2024. [Click here to register](#)



**29 February 2024** – Melbourne, Australia (**28 February 2024** – Minneapolis, MN United States) – **Imricor Medical Systems, Inc. (Company or Imricor) (ASX: IMR)**, the global leader in real-time iCMR cardiac ablation products, today releases its financial results for the full year ending 31 December 2023.

**Commenting on the results, Imricor Chair and CEO, Steve Wedan said:** “There is a lot happening at Imricor in 2024. As I pause to reflect on the highlights of 2023, I know that the opportunity right in front of us is due to the significant work that has been done behind the scenes by our incredible team and partners, as well as the support of our shareholders. Shifting an entire field toward the gold-standard imaging capabilities offered by MRI has been an audacious goal for many years. Many thought it would not be possible given the number of tools and products that needed to be developed. At Imricor, we have developed the Advantage-MR EP Recorder/Stimulator; various catheters, sheaths, transseptal needles, dispersive electrodes, sterile cables, accessories, and NorthStar – our advanced 3D mapping system that brings it all together.

“Alongside this internal development work, our partners have developed MRI-compatible defibrillators, ablation generators, 12 lead ECGs, headsets and monitor screens. With this phase of heavy R&D now behind us and the pandemic in the rearview mirror, I couldn’t be more excited to shift gears into the commercial ramp up of the business. As we get this technology into the hands of more and more physicians at key hospitals around the world, it is patients who will ultimately benefit from the promise of faster procedures, higher first-time success rates, and 100% radiation-free treatments. This has been our mission all along.”

**Looking ahead, Mr. Wedan said,** “The strategy for 2024 is a simple one. Firstly, we will reactivate the existing Imricor sites. Once active, we will work closely with our customers to steadily grow volumes at each lab. Secondly, we will aim to sign new sites within our current geographies but also in new markets as the relevant approvals are received. With the clinical data coming out of two global trials, VISABL-VT and VISABL-AFL, we expect the proof points to build further interest and excitement in the space which in turn helps grow the pipeline and achieve the second goal, increasing new customer sites.

“I am encouraged by the opportunities emerging in the Middle East, and we are working closely with our distributors to get started in these markets where a modern healthcare system with innovative technology is a high priority. It has been a long road to get here, but I am highly energised by the milestones we can achieve in 2024 and beyond.”

### **FY24 Strategy**

In FY24, Imricor will strategically leverage FDA approval for the VISABL-AFL Trial, paving the way for its entry into the USA, the largest market globally. This milestone will streamline regulatory pathways and unlock a significantly higher reimbursement rate, quadrupling that of certain EU countries. With a focus on expanding treatments, the VISABL-VT Trial will showcase the company's capability in complex ablation within MRI environments, reinforcing its commitment to providing comprehensive ablation solutions. Commercialization efforts will



intensify with the activation of sites across the EU, aiming to grow the installed base and penetrate markets in Australia, New Zealand (ANZ), and the Middle East. Momentum was rebuilt in 2023, and as revenue grows in 2024, Imricor's strategic initiatives will position it for sustained expansion and market leadership.

### **Capital Management and Balance Sheet**

Subsequent to year-end, the Company launched a capital raising initiative comprising two concurrent placements and an entitlement offer. To date, the capital raising has resulted in total gross proceeds of approximately A\$8.6 million, bringing Imricor's pro forma cash balance at 31 December 2023 to A\$9.9 million.

### **Investor Webinar**

An investor webinar will be held to discuss the FY23 results. Details:

Presenting: Executive Chair, President and CEO Steve Wedan and CFO Jonathon Gut.

Time: 9:00am AEDT on Tuesday, 5 March 2024 (4:00pm CST on Monday, 4 March 2024)

To register for the session and for more information on the conference click here:

[https://us02web.zoom.us/webinar/register/WN\\_nU31nIGXTdmvqPbaqS6f4w](https://us02web.zoom.us/webinar/register/WN_nU31nIGXTdmvqPbaqS6f4w)

Investors can submit questions prior to the webinar to [simon@nwrcommunications.com.au](mailto:simon@nwrcommunications.com.au) or do so via the Q&A function on Zoom.

### **Imricor background and strategy**

Imricor is leading the new field of *real-time iCMR cardiac ablations* – that is, cardiac ablations guided by real-time magnetic resonance imaging (MRI), rather than by conventional x-ray fluoroscopy. iCMR (*interventional cardiac magnetic resonance*) is the term used to describe such interventional procedures performed in conjunction with MRI. The goal is to provide faster, safer, and more effective treatments of cardiac arrhythmias compared to conventional means.

Imricor is the only company in the world that provides MRI-compatible consumable devices, such as single-use ablation catheters, required to perform cardiac ablations in an iCMR lab.

Benefits of real-time iCMR cardiac ablations are derived from the superior imaging capabilities of MRI compared to x-ray, especially when it comes to imaging the heart and vascular structures which are largely invisible to x-rays. Real-time iCMR also reduces repeated exposure to dangerous x-ray radiation.

Imricor's strategy to grow the field of real-time iCMR cardiac ablations worldwide is built on two actions: to increase the number of iCMR sites across the world and to increase the number of procedures doctors can perform at each iCMR site using Imricor's consumable products.

Key drivers to growing the number of iCMR sites include:

- Existing iCMR sites commencing procedures and presenting/publishing on their experiences
- Growing the Company's footprint across different countries and regions, enabling access for those seeking care and creating competitive pressures between hospitals

- Showing progress toward performing complex ablation procedures, such as ventricular tachycardia (VT) ablations, which increases the utility and demand for iCMR ablations
- Engaging with new physicians to educate them on the benefits of iCMR ablations
- Working with MRI manufacturers to help drive adoption
- Expanding regulatory approval beyond Europe and the Middle East, including the US and ANZ.

Key drivers to increasing the number of iCMR ablation procedures doctors can perform include:

- Development of additional consumable products required for new procedures such as VT ablations
- Partnering with 3<sup>rd</sup> parties to deliver auxiliary equipment needed for new procedures
- Demonstrating clinical effectiveness through clinical trials
- Receiving regulatory approval to market devices for the new indications

As of today, the Company's additional consumables are fully developed and approved for clinical trial use, as are all 3<sup>rd</sup> party devices required for complex ablations.

## **ENDS**

Authorised for release by Steve Wedan, Executive Chair, President, and CEO.

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### **About Imricor**

Imricor Medical Systems, Inc. (ASX:IMR) is a leading developer of innovative MRI-compatible medical devices which can be used to carry out real-time iCMR cardiac ablation procedures. Headquartered in the US, Imricor seeks to make a meaningful impact on patients, healthcare professionals, and healthcare facilities around the world by increasing the success rates and bringing down the overall costs of cardiac ablation procedures.

### **Imricor's Products**

Imricor is a pioneer and leader in developing MRI-compatible products for cardiac catheter ablation procedures, and believes it is the first company in the world to bring commercially viable and safe MRI-compatible products to the cardiac catheter ablation market.

The Vision-MR Ablation Catheter is the Company's prime product offering, specifically designed to work under real-time MRI guidance, with the intent of enabling higher success rates along with a faster and safer treatment compared to conventional procedures using x-ray guided catheters. The Vision-MR Ablation Catheter has been approved in the European Union and the Kingdom of Saudi Arabia with an indication for treating type 1 atrial flutter. Imricor intends to seek approval for expanded indications in the future. The Company is also pursuing the required regulatory approvals to place its key products on the market in Australia, the U.S., and other Middle East countries.

The Company has also obtained approval within the EU and Middle East for the sale of the Advantage-MR EP Recorder/Stimulator System and its consumable product, the Vision-MR Dispersive Electrode.

Imricor sells its capital and consumable products to hospitals and clinics for use in Interventional Cardiac Magnetic Resonance Imaging (iCMR) labs, in which ablation procedures using the Vision-MR Ablation Catheter can be performed. An iCMR lab is an interventional lab that is fitted with MRI equipment for use in cardiac diagnostic and interventional procedures. The installation of iCMR labs is driven primarily by MRI equipment vendors working

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collaboratively with Imricor. Vendors such as Koninklijke Philips N.V. and Siemens Healthcare GmbH help to target certain sites and support the design and construction of iCMR labs for those sites.

### Foreign Ownership Restrictions

Imricor's CHES Depositary Interests (**CDIs**) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (**Securities Act**) for offers which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. As a result of relying on the Regulation S exemption, the CDIs are 'restricted securities' under Rule 144 of the Securities Act. This means that you are unable to sell the CDIs into the US or to a US person for the foreseeable future except in very limited circumstances after the expiration of a restricted period, unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. To enforce the above transfer restrictions, all CDIs issued bear a 'FOR US' designation on the Australian Securities Exchange (**ASX**). This designation restricts any CDIs from being sold on ASX to US persons. However, you are still able to freely transfer your CDIs on ASX to any person other than a US person. In addition, hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

### Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's management's beliefs, assumptions and expectations and on information currently available to management. All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, EU commercial market acceptance and EU sales of our product as well as our expectations with respect to our ability to develop and commercialise new products. Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Imricor does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Imricor may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

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